Norman C. Kleinberg
Theodore V. H. Mayer
William J. Beausoleil
HUGHES HUBBARD & REED LLP
One Battery Park Plaza
New York, NY 10004-1482
(212) 837-6000

Paul F. Strain
M. King Hill, III
David J. Heubeck
Michael B. MacWilliams
VENABLE LLP
Two Hopkins Plaza, Suite 1800
Baltimore, MD 21201
(410) 244-7400

Attorneys for Defendant Merck & Co., Inc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	)	
	)	MDL NO. 1789
	)	1:06-md-1789 (JFK)
This document relates to All Actions	)	
	)	

MEMORANDUM OF LAW OF DEFENDANT MERCK & CO., INC. IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF DOCUMENTS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

Rules

Defendant Merck & Company, Inc. ("Merck"), by its undersigned counsel, hereby files this memorandum in opposition to Plaintiffs' Motion to Compel Production of Documents.

I. INTRODUCTION

More than one year after the issue first crystallized, without demonstrating any cause, let alone the requisite "good cause," Plaintiffs seek to compel the production of what would likely be hundreds of thousands, if not millions, of additional pages of documents irrelevant to the jaw-related injuries they allege, covering a period of time in which no one recognized any potential link between jaw bone injuries and oral bisphosphonates such as FOSAMAX® (hereinafter, "Fosamax"). Plaintiffs make this demand against the backdrop of the more than one million pages Merck has already produced – without regard to date – from the sources most likely to reveal whether there is any basis in fact for Plaintiffs' unfounded proposition that Merck was or should have been on notice of the alleged risk prior to the first public reports suggesting an association between osteonecrosis of the jaw ("ONJ") and bisphosphonates. Those documents include:

- The official Fosamax Investigational New Drug ("IND") and New Drug Application ("NDA") files;
- IND/NDA-related internal correspondence;
- Adverse Experience Review Team (AERT) minutes;
- Periodic Safety Update Reports (PSURs);
- Fosamax Project Team and Product Development Team meeting minutes;
- Background documentation from ONJ worldwide adverse event ("WAES") reports; and
- The custodial files of senior Merck personnel with direct responsibility for Fosamax-related post-marketing surveillance, clinical research, preclinical research, clinical trial, and FDA submissions and communications.

These materials offer no support for Plaintiffs' wholly speculative assertion that the additional documents they seek *may* provide relevant information.

The 2003 date limitation that Merck declared to the Plaintiffs more than fifteen months ago is neither "arbitrary" nor "irrational." (*See* Mem. Law Supp. Pls.' Mot. Compel Produc. Docs. (hereinafter "Pls.' Mem.") at 10.) The 2003 date limitation follows from simple logic: Because there was no suggestion of an association between bisphosphonates and jaw injury prior to September 2003, there is no reason to believe that prior to that date anyone anywhere within Merck had created, received, or contemplated any documents relating to such an alleged association. Unless there is something "rational" about spending millions of dollars to search for and review millions of pages of documents in a vain effort to "prove the negative" – that is, to prove the absence of that which does not exist – then Merck's approach is not only the best suited to this case, it is the only rational course of action available.

Plaintiffs have previously acknowledged that this MDL is not like, and should not become like, the Vioxx litigation. Yet they are trying to manufacture exactly that by seeking to have millions of pages – the relevance of much of which is beyond "suspect" – collected, reviewed, and produced at an expense out of all proportion to any conceivable value to the litigation. Given the relatively smaller pool of plaintiffs, the exceedingly rare condition alleged, and the specific and limited time period relevant to the inquiry, the focused approach followed since the outset of discovery should continue to carry the day, and Plaintiffs' Motion to Compel should be denied in every respect.

II. BACKGROUND OF THIS DISCOVERY DISPUTE

Plaintiffs' lack of diligence in pursuing the date limitation dispute only now presented to the Court unjustifiably threatens the schedule reflected in CMO #10.

Contrary to Plaintiffs' description of the events leading up to the Motion to Compel, Merck made clear to Plaintiffs in Merck's ***January 2007*** discovery responses that Merck, with limited and specified exceptions, would not search for or produce documents dated prior to 2003:

> Except for the production of documents from the official NDA file for FOSAMAX® and as specifically identified in response to specific Requests below, Merck will not produce any documents or information relating to FOSAMAX® prior to September 2003, the date when osteonecrosis of the jaw ("ONJ") was first reported in the literature as occurring in temporal association with bisphosphonates.

(Ex. 1,[1] Merck's Objections & Resps. to Pls.' First Req. for Produc. of Docs. at Gen'l Objections ¶ 4.)

On March 8, 2007, Merck's counsel met with the PSC's discovery chairs for a day-long meeting to address the discovery issues outlined in the PSC's letter of March 1.[2] The PSC's letter specifically raised the question of the date limitation, and Merck's counsel reiterated Merck's view at the meet-and-confer. (Heubeck Decl. ¶ 5.) On April 27, 2007, Merck's counsel again reiterated and emphasized the date limitation, which was the first substantive issue addressed in the thirteen-page letter tackling the full array of discovery topics then at issue:

> This letter will address the various discovery related issues raised in your March 1, 2007 letter and discussed in greater detail at our March 8, 2007 conference in New York. We are still gathering information concerning some of the topics that were discussed, and we will provide further responses once we have sufficient data to respond.
>
> As we stated at the meeting, it is Merck's view that the scope of discovery should primarily be confined to information directly relevant to the jaw related issues raised in this litigation. This litigation involves a product that is still on the market and concerns a condition that only first surfaced in temporal association with bisphosphonate use in 2003, a fact that the Goss expert report submitted in support of Plaintiffs' class certification claims acknowledges. Accordingly, we have attempted to identify reasonable parameters on the scope of discovery so that the costs and burdens of production are fair and do not outweigh any possible relevance of the materials requested and so that each side fairly shares the costs associated with producing the information requested.

[1] References throughout this Memorandum to "Ex.__" refer to the appropriately numbered exhibit attached to the Declaration of David J. Heubeck filed by Merck concurrently with and in support of this Opposition. Plaintiffs' Exhibits are cited as "Pls.' Ex. __."

[2] The PSC's letter to Merck's counsel providing "an outline of the major issues of the PSC to [Merck's] objections and responses to Plaintiffs' first set of interrogatories and requests for production" asked Merck to "explain the reasonable basis upon which you intend to completely exclude all discovery prior to 'September 2003,' which is allegedly the date when ONJ was first reported in the published literature." (Ex. 2, Mar. 1, 2007 letter from S.A. Sanford and J. Green (PSC Discovery Committee Co-Chairs) to D.J. Heubeck and W.J. Beausoleil, at 1, 3.)

(Ex. 3, Apr. 27, 2007 letter from D.J. Heubeck to J.F. Green and S.A. Sanford, at 1.)

Notably, Plaintiffs' Memorandum all but ignores the April 27 letter,[3] as if it was merely the first in a series of communications that somehow left the PSC uncertain as to Merck's position.[4] The reality, however, is that Merck declared its position in January 2007, reaffirmed that position in March and April 2007, and never waivered.[5] Thus, when Plaintiffs suggest that the parties' disagreement on this issue has only recently reached the point where the Court's assistance is required, the Court should recognize that the landscape framing this issue has changed not one whit since April 27, 2007.

Plaintiffs' lack of diligence in this regard must be viewed in the context of the schedule that this Court ordered. The Court directed that fact discovery in the early trial cases conclude by August 1, 2008, a date less than twelve weeks away. The practical effect of the "relief" requested by Plaintiffs at this late date would be to derail an orderly discovery process designed to meet that deadline. The parties are already immersed in fact witness depositions that will continue from now until the August deadline in order to meet the requirements of CMO #10, which contemplates expert discovery and further preparation of the three "bellwether" trials proceeding apace immediately thereafter. If Plaintiffs' request for generalized "relief" from the 2003 date limitation is granted, the August 1, 2008 deadline for the conclusion of fact discovery in the early trial cases is unlikely to stand, as the additional productions might well entail a

[3] Plaintiffs refer to Mr. Heubeck's letter only in a citation in support of the assertion that "the parties have continued to confer in order to resolve discovery disputes." (*See* Pls.' Mem. at 5.)

[4] Adding to the confusion is the Plaintiffs' suggestion that the ***April 27***, 2007 letter reflects an ongoing effort to resolve differences that surfaced only ***after*** Merck's production of documents on ***May 29***, 2007. (*See* Pls.' Mem. at 5 (referring to the April 27, 2007 letter as an example of efforts to confer that occurred "since that time [when Merck produced documents on May 29, 2007]").)

[5] The December 7, 2007 letter cited in the Plaintiffs' Memorandum as an example of the parties' "continuing" efforts "to confer in order to resolve discovery disputes" makes no mention of the date limitation issue. (*See* Pls.' Ex. C.)

substantial doubling back on discovery efforts otherwise completed.[6] Consequently, Plaintiffs' Motion to Compel essentially amounts to a motion to modify the schedule ordered in CMO #10.

Under Federal Rule of Civil Procedure 16(b)(4), a scheduling order may be modified "only for good cause and with the judge's consent." "[W]ith respect to the Rule 16(b) standard, 'good cause' depends on the diligence of the moving party.'" *Kassner v. 2nd Avenue Delicatessen Inc.*, 496 F.3d 229, 243 (2d Cir. 2007) (quoting *Parker v. Columbia Pictures Indus.*, 204 F.3d 326, 340 (2d Cir. 2000)). Where a motion to compel "would serve as a vehicle to circumvent the court-imposed discovery deadline without any reasonable justification to do so," denial is proper. *See Cramer v. Fedco Automotive Components Co.*, 2004 WL 1574691, at *3 (W.D.N.Y. May 26, 2004) (Ex. 4).

A threshold question is whether Plaintiffs have proceeded diligently so as to justify the disruption of the Rule 16 schedule. In *Zivkovic v. Southern California Edison Co.*, the Ninth Circuit explained that "[t]he pretrial schedule may be modified 'if it cannot reasonably be met despite the diligence of the party seeking the extension.' . . . . If the party seeking the modification 'was not diligent, the inquiry should end' and the motion to modify should not be granted." 302 F.3d 1080, 1087 (9th Cir. 2002) (quoting *Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 608 (9th Cir. 1992)). A delay of a year evidences a lack of diligence. *See, e.g.*, *Justin v. City and County of San Francisco*, 2008 WL 544466, at *4 (N.D. Cal. Feb. 26, 2008) (Ex. 5) (no good cause where "Plaintiffs ha[d] known, at a minimum, for almost one year of their need to seek the Court's permission to extend the discovery cut-off"). Indeed, courts refuse to modify their Rule 16 pre-trial schedules where the moving party has failed to act for a far shorter

[6] Plaintiffs' counsel already have indicated their intention to reopen the deposition of Dr. Anastasia Daifotis in the event that additional discovery is compelled. (Heubeck Decl., ¶ 9.) The suggestion that Plaintiffs are somehow justified in revisiting depositions of Merck personnel after Plaintiffs sat on their hands for more than twelve months with respect to such a key issue is both troubling and somewhat perplexing.

amount of time than Plaintiffs have delayed here. *See, e.g.*, *Zivkovic*, 302 F.3d at 1087-88 ("Zivkovic's counsel did not seek to modify that order until four months after the court issued the order. Zivkovic did not demonstrate diligence in complying with the dates set by the district court, and has not demonstrated 'good cause' for modifying the scheduling order.").

From the outset of this MDL, the Court advised counsel to proceed "expeditiously." (Ex. 6, Sept. 14, 2006 Status Conf. Tr. at 3.) Ignoring the Court's admonition, Plaintiffs instead waited more than a year before moving for the "relief" now sought and belatedly seek to turn back the clock without any good cause for doing so.

III. MERCK'S DOCUMENT PRODUCTION TO DATE

Merck has already produced nearly 1.5 million pages of the most pertinent Fosamax-related documents.

With respect to those electronic and hard copy document populations that Merck has agreed to search, Plaintiffs' suggestion that Merck has ignored the osteomyelitis and other jaw-related injuries Plaintiffs allege is not correct. The universe of potentially responsive documents was assembled using the following set of search terms, to which the PSC has not objected:[7]

> Fosamax or Alendronate or Bisphosphonate* or Aredia or Pamidronate or Zometa or "Zoledronic Acid" or "Zolendronic Acid" or Zoledronate or Actonel or Risedronate or Boniva or Bondronat or Ibandronate or Didronel or Etidronate or Bonefos or Clastoban or Clasteon or Ostac or Clodronate or "Phossy jaw" or phossy or "Paget's Disease" or paget* or "Dead bone" or "Nude bone" or "Necrotic bone" or Skelid or Tiludronate or Incadronate or Minodronate or Nerixia or Neridronate or Olpadronate or Piridronate or Cimadronate or Medronate or Osteo* or AVN or *necrosis or ONJ or ORN or FPD or NOF or NORA or GIOP or WOOO or FOSIT or FOCAS or IN-FOCAS or FORE or OSR or Gum or Tooth or Teeth or Jaw or Mandible or "Office of Drug Safety" or Maxilla or EPIC or FLEX or FIT w/50 (study or trial or clinical) or EFFECT w/50 (Evista or Raloxifene) or ALN or 0217 or MK-217 or MK217 or MK-217A

[7] The listing that follows reflects the search terms disclosed to the PSC in Merck's April 27, 2007 letter, as modified at the request of the PSC in December 2007. The only search term requested by the PSC at that time that was not included is "fx" (i.e., "fracture"), which was excluded in light of the frequency with which it generated "false hits." (*See* Ex. 7, Dec. 27, 2007 e-mail from D.J. Heubeck to J. Grand.)

or MK-0217A or 217A or MK217A or "oral hygiene" or "oral surgery" or mouth or dentist or dental or extraction or decay.

Merck's counsel has more than once offered Plaintiffs' counsel the opportunity to comment on or add to this list of terms. After identifying and reviewing relevant documents from the universe of documents that "hit" on the above search terms,[8] Merck has produced the following categories of documents dating from 2003 forward, among others:

Category Description	Number of Pages
Osteoporosis Marketing Team materials (including various predecessor groups)	40,552
Promotional materials	10,765
Core set of Fosamax-specific training materials (current materials)	1,157
Fosamax-specific sales training materials	1,641
Labeling meeting minutes	134
Board of Directors meeting minutes	61
Responses to Physician Information Requests (PIRs)	28,555
Fosamax Field Sales Bulletins	3,508
DDMAC correspondence	514
Materials from consultants' meetings held in May 2005 and September 2006	770

(Heubeck Decl. ¶ 8.)

Perhaps more significantly, Merck has produced the following categories of documents without regard to date:

Category Description	Number of Pages
Official Fosamax IND and NDA Filings	856,992

[8] Plaintiffs' suggestion that the additional productions Plaintiffs seek would impose a minimal burden because Merck "has acknowledged in meetings that it has *already collected* documents from the time period at issue (many of which exist in electronic form)" (Pls.' Mem. at 1-2) is more than a bit disingenuous. True enough, Merck has collected some of the earlier documents, but certainly not all of them; and the nub of the issue is hardly the expense of the search for and collection of electronic documents. The real burden, as Plaintiffs well know, is the effort and expense required to review, redact (for privilege, privacy, etc.), and produce relevant documents from the substantial universe of materials identified through the use of those search terms.

Category Description	Number of Pages
IND/NDA-related internal correspondence	109
Adverse Experience Review Team (AERT) minutes	49
Periodic Safety Update Reports (PSURs)	26,634
Fosamax Project Team and Product Development Team meeting minutes	6,992
Background documentation from ONJ WAES reports	1,817

The custodial files of the following Merck personnel have also been produced without regard to document date:

Custodian	Number of Pages
Dr. Arthur Santora, Executive Director, Clinical Sciences, with previous clinical research responsibilities for Fosamax for a number of years	164,317
Dr. Anastasia Daifotis, Vice President, Global Medical Affairs, with previous clinical research responsibilities for Fosamax for a number of years	86,570
Dr. Michael Goldberg, formerly a physician in the Clinical Risk Management and Safety Surveillance group with responsibility for post-marketing surveillance of Fosamax	22,762
Dr. Donald Kimmel, Director of Molecular Endocrinology, responsible for preclinical research for Fosamax for a number of years	60,323
Dr. Anne de Papp, Global Director of Scientific Affairs, with previous responsibilities relating to Fosamax clinical trials	34,534
Dr. Michele Flicker, Senior Director in Merck's Worldwide Regulatory Group who previously acted as the liaison between the FDA and Merck for regulatory submissions and communications relating to Fosamax	49,853

IV. ARGUMENT

A. Plaintiffs Cannot Make the Showing of "Good Cause" Necessary to Compel Production of the Requested Pre-2003 Documents

1. Standard of Review

Fed. R. Civ. P. 26(b)(1) identifies the permissible scope of discovery as follows:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense . . . . For good cause, the court may order

> discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. All discovery is subject to the limitations imposed by Rule 26(b)(2)(C).

Fed. R. Civ. P. 26(b)(1). Plaintiffs attempt to gloss over the important change in approach effected by the 2000 amendments to the Rule. (*See* Pls.' Mem. at 6-7.) Those amendments "narrowed the scope of discovery," *Dunkin' Donuts Franchised Restaurants, LLC v. 1700 Church Ave. Corp.*, 2008 WL 1840760, at *1 (E.D.N.Y. Apr. 23, 2008) (Ex. 8) (denying motion to compel), in the first instance to non-privileged matters "relevant to any party's claim or defense," Fed. R. Civ. P. 26(b)(1); *see also Bowen v. Parking Auth. of the City of Camden*, 214 F.R.D. 188, 194 (D.N.J. 2003) (denying motion to compel and stating that the 2000 amendments "narrowed scope of discovery under the rules generally"). Where, as here, a party wishes to go beyond this narrowed scope to request discovery of matters more broadly "relevant to the subject matter involved in the action," the requesting party must demonstrate good cause and obtain a court order to do so. *Dunkin' Donuts*, 2008 WL 1840760, at *1; *see also World Wrestling Fed'n Entm't, Inc. v. William Morris Agency, Inc.*, 204 F.R.D. 263, 265 n.1 (S.D.N.Y. 2001) (affirming magistrate's denial of plaintiff's discovery request and noting that 'unless expanded by the court for good cause shown, it is intended that the scope of discovery be narrower than it was, in some meaningful way'" (quoting *Surles v. Air France*, 2001 WL 1142231, at *1 n.3 (S.D.N.Y. Sep. 27, 2001)).

As the *Bowen* court explained:

> The 2000 amendment to Rule 26(b) modified a party's access to information, changing the focus from that information 'relevant to the *subject matter* involved in the pending action' to that information 'relevant to the *claim or defense* of any party.'

214 F.R.D. at 194; *see also Johnson Matthey, Inc. v. Research Corp.*, 2002 WL 31235717, at *2 (S.D.N.Y. Oct. 3, 2002) (Ex. 9) (finding no good cause to compel document production and

noting that "Rule 26(b)(1) of the Federal rules of Civil Procedure was amended to narrow the scope of relevancy from 'subject matter' of the action to 'claim or defense of any party'"). Accordingly, the cases cited by the Plaintiffs, all but one of which pre-date the 2000 amendments, are inapposite to the extent that they fail to account for the "good cause" standard governing discovery not relevant to claims or defenses.

"The information sought by [a party] does not become relevant merely because [the party] speculates that it might reveal useful material." *Surles*, 2001 WL 1142231, at 2 (Ex. 10) (upholding magistrate's finding of no good cause and denial of motion to compel); *see also In re Alliance Pharms. Secs. Litig.*, 1995 WL 51189, at *1 (S.D.N.Y. Feb. 9, 1995) (Ex. 11) ("[D]iscovery requests . . . cannot be based on pure speculation."). Therefore, "speculations do not rise to the level of good cause." *Surles*, 2001 WL 1142231, at *2. The good cause standard instead "requires the movant to point to specific facts." *Id.* (internal quotation marks omitted). As explained in detail below, none of the information now sought by Plaintiffs is relevant to their jaw-related claims or Merck's defenses to those claims. As a result, Plaintiffs are required to show "good cause" meriting the production of each category of information Plaintiffs seek.

Additionally, the explicit cross reference in Rule 26(b)(1) to the provisions of Rule 26(b)(2)(C) further constrains the overbroad scope of discovery sought by the Plaintiffs. In particular, Rule 26(b)(2)(C)(iii) empowers this Court to limit the extent of discovery if the Court determines that "the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving

the issues." Fed. R. Civ. P. 26(b)(2)(C)(iii).[9] Thus, even where the discovery sought is determined to be relevant to the claims and defenses, the inquiry should be curtailed where the effort required outpaces the likely payback of expending that effort. Discovery requests that are premised on "farfetched" theories of relevance or are otherwise designed as a "fishing expedition" to discover additional theories of liability are not permissible. *See Lyeth v. Chrysler Corp.*, 929 F.2d 891 (2d Cir. 1991) ("[T]he district court did not err when it observed that Chrysler was simply 'engaging in a fishing expedition in an attempt to determine if there is some basis, however farfetched, to prosecute a claim of bias.'").

2. The 2003 Date Limitation Is Logically Tailored to Plaintiffs' Claims

Plaintiffs complain that the 2003 date limitation was "unilaterally" and unjustifiably imposed by Merck without regard for the hypothetical possibility that a temporal association between bisphosphonates and jaw bone injuries may have been recognized by Merck or others at an earlier point in time. That limitation, however, was by no means "unilateral" in the sense that Plaintiffs suggest. To the contrary, Plaintiffs' own expert has expressed the unequivocal view that "[t]he condition of bisphosphonate-associated ONJ was not known before 2003." (Ex. 12, Goss Aff. Supp. Pls.' Mot. Class Cert. ¶ 35.) Plaintiffs now seek to contradict their own expert based upon pure speculation that somehow, somewhere prior to 2003 there where clues to some alleged association between bisphosphonates and jaw bone injuries that Merck could or should have recognized and acted upon. Presumably putting their best foot forward in support of this proposition, Plaintiffs' Memorandum proffers a 1995 paper entitled *Failure of Osseointegrated Dental Implants After Diphosphonate Therapy for Osteoporosis: A Case Report*" ("Starck paper"). (*See* Pls.' Mem. at 9.) That paper provides not the slightest support for Plaintiffs'

[9] Rules 26(b)(2)(C)(i) and (ii) also weigh in the balance where the discovery sought is "unreasonably cumulative or duplicative" or where "the party seeking discovery has had ample opportunity to obtain the information by discovery in the action."

position. In fact, the case reported by Starck (1) involved a non-nitrogenous bisphosphonate (etidronate), and (2) did not involve ONJ or any condition akin to ONJ.

In fact, Plaintiffs themselves know better. In the paragraph in their Memorandum immediately preceding the discussion of the Starck paper, Plaintiffs emphasize that "Fosamax is a nitrogen-containing (nitrogenous) bisphosphonate . . .," and that "[i]n August 2004,[10] the FDA concluded that an increased risk of ONJ is a class effect of all nitrogenous bisphosphonates . . . ." (Pls.' Mem. at 9.) This "class effect" theory was likewise a point of emphasis in Plaintiffs' "position paper" submitted to the Court on November 21, 2006, in which Plaintiffs' Counsel emphasized the "critical" distinction between nitrogenous and non-nitrogenous bisphosphonates: "There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. . . . The presence of the nitrogen atom in the Fosamax formulation is critical to understanding the dangers of Fosamax and the long-range risks that Fosamax use presents." (Pls.' Ex. J, at 1-2.) Plaintiffs' argument for the elimination of the date restriction, therefore, requires Merck to have disregarded this "critical" distinction between etidronate and Fosamax.

Moreover, Plaintiffs' hindsight-aided conjecture requires Merck to have ignored in addition the fact that the case reported by Starck involved the failure of dental implants as a result of "extensive osteolysis" – that is, an extensive *increase* in the amount of bone resorption[11] – whereas Fosamax works by *inhibiting* (i.e., reducing) bone resorption.[12] Plaintiffs' argument that Merck should search documents prior to 2003 is thus based on the exceedingly remote possibility that Merck (and/or others) may have recognized the putative

[10] Merck disputes that the FDA came to any conclusions about Fosamax and ONJ in August 2004.
[11] *See, e.g.*, Ex. 13, 1 ANTHONY S. FAUCI ET AL., HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 614 (14th ed. 1998) ("Cancer in the bone may produce osteolysis, osteogenesis, or both. Osteolytic lesions result when the tumor produces substances that can directly elicit bone resorption . . . .").
[12] *See* Ex. 14, Fosamax Package Insert at 3.

connection between Fosamax and ONJ as a result of a single paper reporting a condition resulting from the antithesis of Fosamax's mechanism of action that was caused by a three-month course of therapy with a medication in a different class of bisphosphonates that lacks the nitrogen atom described as "critical" to the alleged risk of long-term Fosamax therapy.[13]

Plaintiffs' other suggested indicator of a knowable connection between Fosamax and ONJ is the Iizuka article entitled "*Alveolar bone remodeling after tooth extraction in normal and osteopetrotic (ia) rats*." That Plaintiffs apparently regard this article as their strongest "notice" evidence is telling, given that:

- The study was performed in genetically mutated rats – not humans.
- The mutated rats were bred to have a disease known as osteopetrosis – not osteoporosis. Osteopetrosis involves an inactivation of osteoclasts – osteoporosis involves an imbalance in the activity of osteoclasts and osteoblasts.
- The mutated rats were NOT given Fosamax or any other bisphosphonate.
- The mutated rats did NOT develop necrosis in their jaws.

As this study of genetically mutated rats does not involve the effects of a bisphosphonate and does not reference any necrotic or dead bone, it should not be the impetus that allows for the production of documents beyond the hundreds of thousands of pages of materials already produced that specifically deal with the key scientific and regulatory decisions prior to 2003.

Plaintiffs press this implausible speculation despite the more than 1.2 million pages of documents already produced to Plaintiffs that would have revealed any possible scenario that might actually have unfolded according to Plaintiffs' hypothesis. Those documents include not

[13] Also noteworthy in this context is the fact that the conclusion of the Starck paper – that "it is advisable to avoid diphosphonate therapy in patients who have previously undergone implant placement" (Pls.' Ex. L at 76) – runs contrary to the conclusions of Plaintiffs' lead expert, Dr. Marx, who has opined that invasive dental procedures, including the installation of implants, may be performed as long as they are completed before the end of the third year of bisphosphonate therapy. (Ex. 15, Aff. Robert E. Marx Supp. Pls.' Mot. Class Cert. ¶ 47.) Similarly incongruous with Plaintiffs' reliance on the Starck paper, in which the patient's dental implants apparently failed within a few months of the inception of bisphosphonate therapy, is Dr. Marx's opinion that Fosamax poses no increased risk to patients until after the third year of continuous treatment. (*See, e.g.*, Ex. 16, June 1, 2007 Marx Dep. at 77, 80, 221.)

only the entire official IND and NDA files dating back to 1988 and 1995, respectively (856,992 pages), but also the more than 380,000 pages of documents produced (also without regard to date) from the custodial files of the Merck personnel most likely to have been aware of any such causal theory or connection if indeed one had been recognized at any time prior to 2003. Moreover, the 26,634 pages of Periodic Safety Update Reports and more than 50,000 pages of Periodic Adverse Event Reports produced to Plaintiffs (*see* Heubeck Decl. ¶ 8) reflect the adverse events reported to Merck since Fosamax entered the market. Nonetheless, Plaintiffs point to nothing more compelling than a six-page article discussing delayed healing of extraction sites in genetically defective rats.[14] Such a striking contrast plainly demonstrates the absence of "good cause," rather than the existence of "good cause," particularly when the Court takes into account the substantial costs of re-doing this discovery and the resulting disruption to the existing schedule.[15]

Plaintiffs' argument premised upon the relative efficacy of Fosamax (*see* Pls.' Mem. at 10) fares no better in this regard. Preliminarily, Merck has already made available to Plaintiffs all of the scientific data upon which Merck relied to support the FDA-approved indications, as well as the custodial files for Merck scientists knowledgeable about the efficacy data. Moreover, the only "risk-benefit profile" germane to this discussion is that which compares the information

[14] As a result of Merck's search for and production of documents containing the term "osteomyelitis," Plaintiffs are aware of the two reports of osteomyelitis of the mandible that occurred in Fosamax clinical trials. (*See* Ex. 17, Apr. 2005 e-mails (filed under seal).) Merck can only speculate that the reason these cases went without mention in Plaintiffs' opening memorandum is that one of the two occurred in a placebo group. The equal distribution of a grand total of two osteomyelitis of the mandible cases in the clinical trials hardly augurs in favor of Plaintiffs' alleged association between Fosamax and ONJ (or osteomyelitis).

[15] Given the absence of any showing by Plaintiffs that the further discovery they seek would likely lead to the production of *any* admissible evidence, Merck has addressed the burdens that the putative discovery would impose on Merck in general terms and by example. (*See* Heubeck Decl. ¶ 28.) Merck is prepared to expend the additional effort necessary to quantify such burdens more comprehensively and more precisely in the event and to the extent that the Court contemplates ordering any of the discovery sought, notwithstanding Plaintiffs' failure to make the threshold showing of relevance warranting that exercise. Similarly, shifting to Plaintiffs of the substantial costs associated with the additional productions they request is a further factor that would need to be addressed by the Court.

concerning the risks about which Plaintiffs complain (ONJ and similar jaw conditions) to the efficacy information available during the period of time in which the risks were known (late 2003 and later). Plaintiffs' prescribing physicians could not have factored into the prescribing decision the frequency or severity of an unknown (and unproven) risk. Plaintiffs cannot credibly suggest (as they attempt to do at page 12 of their Memorandum) that they might not have been prescribed Fosamax if only their prescribers had been able to compare additional efficacy information against the unknown incidence of an unidentified risk.[16] Plaintiffs' demand for additional efficacy information beyond that already contained in the various iterations of the Fosamax label, the hundreds of thousands of pages of the official NDA file produced by Merck, and the custodial files of the scientists involved in assessing its efficacy is thus the consummate fishing expedition – the quest for information that can have no bearing whatsoever on the viability of the claims asserted.

In the hundreds of thousands of pages of produced documents that pre-date 2003, there is no evidence suggesting that Merck was subjectively aware of any alleged connection between bisphosphonates and ONJ prior to 2003. Even Plaintiffs' self-proclaimed world-renowned experts profess that the world was ignorant of Plaintiffs' alleged "bisphosphonate-induced ONJ" until 2003. Consequently, Plaintiffs' quest for Merck's pre-2003 sales and marketing-related documents, labeling committee materials, Board of Directors meeting minutes, and DDMAC correspondence is baseless. There is no conceivable way in which Merck's marketing and sales personnel, its Board of Directors, its labeling committees, or its FDA liaisons could possibly

[16] Plaintiffs argue without explication that pre-2003 efficacy evidence is "relevant to plaintiffs' failure to warn and design defect claims" (Pls.' Mem. at 12), but the alleged defect in Fosamax and the risk about which Merck allegedly failed to warn Plaintiffs trace exclusively to Plaintiffs' alleged jaw injuries, which came to be associated with bisphosphonates only since 2003. As a result, Plaintiffs' arguments yet again meet the same fate – the only materials even potentially relevant to Plaintiffs' claims are those dated 2003 and later.

have addressed – among themselves or in communications with third parties – an alleged risk of which Merck's scientific and regulatory affairs personnel were unaware.[17]

3. Plaintiffs Lack Good Cause with Respect to Each Category of Documents Sought

The absence of actual knowledge – within or outside of Merck – of the alleged link between Fosamax and Plaintiffs' claimed injuries dispenses with all of the categories of documents addressed at pages 11 through 16 of Plaintiffs' Memorandum (subheadings A through G). Not one of those categories of documents, prior to 2003, comprises materials relevant to the jaw-related injuries about which Plaintiffs complain. Certain aspects of Plaintiffs' arguments regarding those categories, however, deserve more particularized treatment.

Field Sales Bulletins. Plaintiffs offer as justification for the discovery of Field Sales Bulletins pre-dating 2003 the example of "Field Bulletins [utilized by Merck] to instruct its sales representatives on how to address physicians' concerns about the cardiovascular safety of [Vioxx]." (Pls.' Mem. at 11.) The analogy is patently defective in light of the fact that Fosamax prescribers were not and could not have been raising concerns with Merck about the jaw-related safety concerns that no one in the world recognized. Merck has produced more than 3,500 pages comprising all of the Fosamax-related Field Sales Bulletins (and their attachments) issued since January 2003, a period of approximately five years. Plaintiffs' Memorandum criticizes Merck for failing "to address whether, prior to 2003, Merck internally discussed any potential relationship between bisphosphonate therapy and ONJ or other jaw conditions," and for "ignor[ing] important issues that have been raised in this litigation and which are highly relevant to the claims and defenses asserted by the parties . . . ." (Pls.' Mem. at 11-12.) The Plaintiffs,

[17] The fact that Merck's scientists and regulatory liaisons were unaware of such alleged risks prior to 2003 is evident from the meeting minutes of the Adverse Event Review Team, the Fosamax Product Development Team, and the Fosamax Project Team, all of which were produced without regard to date and none of which reflect the discussion of ONJ or jaw-related injuries prior to 2003.

however, have no reasonable belief that even one of those additional documents – collected, reviewed, and produced at great expense – would be relevant to either the jaw-related claims advanced by Plaintiffs or Merck's defenses to those claims.

Physician Information Requests (PIRs). All of the "concepts" addressing PIRs dated 2003 and later have been produced – some 28,555 pages. Going beyond that which was necessary in an effort at compromise, Merck has also agreed to produce without regard to the pre-2003 date restriction all of the responses to PIRs sent to plaintiffs' prescribing physicians.[18] Beyond that, there simply is no rationale, let alone "good cause," for compelling the collection, review and production of *all* of the Fosamax-related PIRs sent to *all* physicians for the entire time that Fosamax has been on the market, which is what Plaintiffs have sought. Such a production would likely comprise hundreds of thousands of additional pages, not a single page of which could reasonably be expected to address the conditions or risks about which Plaintiffs complain.

Sales Training Materials. Plaintiffs' complaint that Merck has agreed to produce only current sales representative training materials reflects an apparent misunderstanding. As set forth above (*see supra* p. 7), Merck has already produced Fosamax-specific sales training materials dated 2003 and later. Similarly, Merck has agreed to produce "generic" sales training materials covering the same period, and that production is expected by month's end, if not sooner.

Materials Related to Fosamax Labeling. Plaintiffs argue that pre-2003 labeling materials may "provide insight into the dialogue between Merck and regulatory agencies relating to the safety and efficacy disclosures for Fosamax." (Pls.' Mem. at 15.) As set forth above, the only

[18] These productions are restricted to documents dated earlier than six months after the plaintiff's last Fosamax prescription.

"safety and efficacy disclosures for Fosamax" relevant to Plaintiffs' claims are those addressed to the jaw-related issues circa 2005 and thereafter. Nonetheless, the suggestion that Plaintiffs lack labeling-related information going back in time ignores the thousands of pages of the NDA production addressed to labeling issues, including the Fosamax labels, draft or final, submitted for FDA approval, as well as the custodial files for individuals who would have been involved in labeling issues.[19] (*See* Heubeck Decl. ¶ 8.)

Likewise, Plaintiffs' demand that Merck collect all draft labeling materials separate and apart from Merck's NDA and custodial file productions is both unreasonable and impracticable, as explained to Plaintiffs more than a year ago:

> Labeling Drafts. Our investigation has shown that there is no file specifically maintained at Merck for the purpose of retaining drafts of labels. The official NDA file for Fosamax contains past, current, and proposed labeling for the medication. To the extent that an individual custodian's file contains draft labeling information relating to ONJ, then those documents will be produced . . . as part of the later production of individual custodial files.

(Ex. 3, Apr. 27, 2007 letter from D.J. Heubeck, at 8, ¶ 17.) Plaintiffs' now-familiar refrain that such materials "may contain admissions regarding the safety and efficacy of the drug," and for that reason are "highly relevant" (Pls.' Mem. at 21-22) fails to identify sufficiently to establish good cause what more Plaintiffs hope to receive that Merck has not already produced.

As Plaintiffs note, Merck has (since at least as early as January 2007) made clear to Plaintiffs that it is not Merck's intent to collect, review, and produce documents located outside the United States. Despite the fact that Plaintiffs have not established any plausible connection between Merck's overseas regulatory activities and the injuries Plaintiffs' claim to have suffered, Merck has stated its intention to produce documents related to ex-US labeling and other issues to the extent that they relate to the injuries claimed by Plaintiffs and are found in the custodial files

[19] Also noteworthy in this regard is the substantial efficacy and risk information addressed in those labels, as reflected in the exemplar attached hereto as Exhibit 14.

of Merck's domestic personnel. (*See* Ex. 1, Merck's Objections & Resps. to Pls.' First Req. for Produc. of Docs. at Gen'l Objections ¶ 13; Ex. 3, Apr. 27, 2007 letter from D.J. Heubeck, at 9.) As Merck has explained to Plaintiffs, those custodial productions will include the custodial files of two persons "who were primarily responsible for international regulatory issues relating to Fosamax during the 2003- May 2006 time period" (Ex. 3 at 9-10); *i.e.*, the period of time during which the Fosamax label was amended so as to address ONJ. The burden of going beyond that which Merck has offered to produce exceeds any reasonably expected return on that effort. The same is true with respect to the foreign subsidiary animal or lab testing or analysis: Merck cannot be expected to undertake even the effort required to locate such materials beyond those included in the domestic NDA, particularly given that such materials would have nothing whatsoever to do with ONJ.

Board of Directors Meeting Minutes. Plaintiffs nakedly argue that "[e]xecutive decisions [in the years prior to 2003] relating to the development, testing, and marketing of Fosamax are highly relevant to plaintiffs' claims . . ." (Pls.' Mem. at 15), whereas the naked truth is that executive decisions relating to the development, testing, and marketing of Fosamax in the years prior to 2003 have almost nothing to do with Plaintiffs' claims. Merck has produced Fosamax-related board minutes dated 2003 and thereafter, and no good cause exists for reaching any farther back in time.

DDMAC Correspondence. Merck's correspondence with the FDA's Division of Drug Marketing, Advertising, and Communications prior to 2003 could not be relevant to Plaintiffs' jaw-related claims. Moreover, prior to 2003, Merck could not have "demonstrated a pattern and practice of misleading physicians" about a risk of which Merck was unaware. Plaintiffs have offered just one example (from 1997) of the "multiple occasions" on which Merck was

supposedly chided by the FDA for misleading promotions, and Plaintiffs make no effort to explain how that example, alone or in combination with others, rises to the level of a "pattern or practice" of misleading physicians. Here, again, Plaintiffs are merely fishing for opportunities, in the absence of relevant facts, to sling some mud in Merck's direction.

Materials Relating to the Osteoporosis Marketing Team (OMT) and its Predecessors. As is the case with regard to Merck's sales personnel, Merck's marketing teams could not possibly have contemplated the parameters of safety issues of which Merck's scientists were subjectively unaware. Consequently, there is no utility whatsoever, let alone "good cause," for compelling the collection and review of what (given the broad search terms) would be more than 160,000 additional pages of OMT hard-copy materials alone. (*See* Heubeck Decl. ¶ 28.)

Prescribing Physician and Sales Representative Discovery.

Merck has agreed to produce the following materials reflecting communications between Merck and plaintiffs' prescribing physicians as part of the case-specific discovery:

> Mercury: Provides Physician Information Request (PIR) response letters sent to Plaintiff's prescribing physicians. (Data available: approx. 1997 – present).
>
> FACTS: Provides information about calls by Merck Professional Representatives on Plaintiff's prescribing physicians. To the extent applicable and available within FACTS, this includes call details, call notes, call topics, customer beliefs, PIRs, attendance at Merck sponsored programs, responses to questions, promotional items and messages, "My Call" presentations, sample sends, and voucher information. (Data available: approx. 1998 – present).
>
> Cornerstone/OMNI: Tracks contacts with Merck's National Service Center by Plaintiff's prescribing physician and by Plaintiff. (Data available: approx. 1996 – present).
>
> ROME: Searches for letters on line that were sent to Plaintiff's prescribing physician. (Data available: approx. 2002 - present).
>
> SAM: Provides information about sample distributions to Plaintiff's prescribing physician. (Data available: approx. 1995 - present).

MAX: Provides information about whether Plaintiff's prescribing physician is included in the MAX database, which includes "thought leaders" and speakers. (Data available: approx. 1996 - present).

AP/JDE: Records payment information to Plaintiff's prescribing physician by Merck. (Data available: approx. 1995 – present).

MCF Foundation Payment Data: Provides information about Merck Foundation payments to Plaintiff's prescribing physician. (Data available: approx. 1990 – present).

MESA/iMED: Provides information about whether Plaintiff's prescribing physician received payments for a speaker program or physician education program. (Data available: approx. 1997 – present, with some sporadic data available for 1994 – 1996).

Consumer Database: Identifies whether Plaintiff's prescribing physician or Plaintiff requested information through the Fosamax.com website. (Data available: 1992 - present).

RIMS: Information that enables Merck to determine if Plaintiff's prescribing physician participated as a clinical investigator for any Fosamax studies. (Data available: approx. 1983 – present).

eRDR Clinical Investigator Search: Provides information about whether Plaintiff's prescribing physician is associated with any Merck clinical trials. (Data available: 1996 – present, sporadic and incomplete data may be available prior to 1996).

(Ex. 3, Apr. 27, 2007 letter from D.J. Heubeck to J.F. Green and S.A. Sanford, at 10-12.) As a function of the information produced, in particular, from the FACTS database, as described above, Plaintiffs will receive the call details, call notes, call topics, customer beliefs, responses to questions, and "My Call" presentations associated with ***all*** of the sales representatives who called on a given prescribing physician (subject to the same restriction noted in footnote 18). Thus, Plaintiffs' complaint that they are left to "make a *blind selection* of 4 sales representatives for a call note production" (Pls.' Mem. at 18) is wholly inaccurate.[20] Plaintiffs have the information to guide their selection of the four representatives in connection with which Merck will then

[20] Likewise, Plaintiffs' complaint that they will have available to them relatively less sales representative information (Pls.' Mem. at 19) is a red herring. Merck does not intend to utilize at deposition or in trial sales representative information that Merck has refused to produce.

make a full personnel file production (including Fosamax-related documents regardless of date) and a custodial file production of the Fosamax-related documents dated from 2003 to the date that is six months after the particular plaintiff's last Fosamax prescription.[21]

The dispute again boils down to the appropriate date restriction. Nothing more need be said about the discoverability of the pre-2003 materials, but Plaintiffs' request for sales representative documents dated more recently than six months after a plaintiff last used or was prescribed Fosamax presents another example of the types of information sought by Plaintiffs that, although perhaps related to the subject matter of the action, cannot possibly be relevant to a party's claim or defense. Prior to the filing of their motion, Plaintiffs did not pretend to argue that such information was relevant to a particular plaintiff's claim; only that "such materials may reflect admissions or Merck's current views regarding causation or warnings." (Ex. 18, Jan. 23, 2008 e-mail from J. Grand to D.J. Heubeck.) That rationale, to the extent it rises above the level of rank speculation, never approaches "good cause."

Finally on the question of sales representative discovery, Plaintiffs request (although they do not specifically argue in their Memorandum) that Merck should produce the custodial files not only of those representatives who called on a plaintiff's prescribing physician, but also of those representatives who called on such prescribers' colleagues. (*See* Pls.' Mem. at 16 ("Plaintiffs have requested production of custodial files for those Merck sales representatives that called on plaintiffs' prescribing physicians *or their offices* . . . ." (italics added)).) To the extent that Plaintiffs are interested in what a prescribing physician may have learned about Fosamax

[21] Merck had understood to this point that Plaintiffs were seeking to depose only two sales representatives per plaintiff, chosen from among the four representatives with respect to whom Merck was asked to make custodial productions. Plaintiffs' Memorandum states that "plaintiffs would then select a *minimum of 2* representatives for deposition," (Pls.' Mem. at 17 (italics added)), seemingly injecting additional uncertainty into the mix. Although the matter is beyond the scope of Plaintiffs' Motion to Compel the Production of Documents, Merck remains committed to its offer to produce two sales representatives per plaintiff, but objects to any effort to depose more than that as unjustifiably burdensome.

from his or her colleagues, the rational approach to that information is to inquire of that prescriber upon deposition, not to put Merck to the burden of producing information concerning sales calls on physicians who may well never have played any role in the care of a particular Plaintiff. Such an obvious fishing expedition hardly reflects the "good cause" sufficient to grant Plaintiffs' Motion.

B. Plaintiffs' Broad-Brush Demand for the "Source Materials" Underlying All Adverse Event Reports Is Unnecessary and Inappropriate

Plaintiffs argue that they require access to the "source documentation" or "source materials" underlying "the Adverse Event Reports relating to Fosamax" because, they claim, such information "will enable plaintiffs' experts to evaluate whether individual adverse events were correctly diagnosed by the reporting physician or Merck." (Pls.' Mem. at 20.) The fact of the matter, however, is that Merck cannot, except at great and unnecessary expense, collect, review, and produce the hundreds of thousands, if not millions, of pages of such information associated with the thousands of adverse events reported in the twelve-plus years since Fosamax was first approved for the US market. Fortunately, such a scattershot approach is unnecessary in the effort to locate the information that Plaintiffs are seeking.

Instead, Plaintiffs already have available to them, through the Periodic Safety Update Reports (PSURs), line-item descriptions of all of the post-marketing adverse events – "serious" and otherwise – reported since 1995. Each of those line items, the collection of which Plaintiffs can search in an effort to identify jaw-related injuries or conditions, is associated with a unique identifier, known as a "WAES" number. The WAES number, in turn, can be traced by Merck back to whatever "source materials" exist for that event. As a result, the straightforward and most efficient path forward on this issue is for Plaintiffs simply to identify, by WAES number,

those specific adverse events for which they seek the available source materials. This approach shares the burden of securing to the Plaintiffs the information they are requesting.

In addition to the "source materials" already produced or available to Plaintiffs, Merck offered *more than a year ago* to run searches calculated to identify the further information Plaintiffs now seek:

> 25. Production of Information from Merck Databases. Merck is willing to search its worldwide database of adverse event reports (NWAES), as well as the clinical trial database (CTS) identified in your March 1 letter, for relevant adverse events identified by Plaintiffs and to provide a line listing of the results of those searches and back-up documentation with respect to the identified events that Merck is able to locate with reasonable efforts. Please provide us with relevant search terms that you propose at your earliest convenience so that we can reach an agreement as to which terms should be included in the search.

(Ex. 3, Apr. 27, 2007 letter from D.J. Heubeck to J.F. Green and S.A. Sanford, at 10.) Plaintiffs never responded to this offer, nor suggested to Merck any relevant search terms. Instead of diligently pursuing the subject according to Merck's proposal, Plaintiffs elected to wait a year and then inexplicably moved to compel.

C. Plaintiffs Have Not Demonstrated Good Cause for Discovery of the Prescribing Information Concerning the Dentists and Physicians Who Have Treated Plaintiffs' Claimed Injuries

In seeking IMS physician-level data with respect to plaintiffs' *treating* physicians, Plaintiffs' argue that

> the extent to which a given plaintiff's treating or prescribing physician prescribed Fosamax or a competitor's bisphosphonate over time, and any changes in their prescribing habits as a result of marketing practices or availability of risk information related to Fosamax, are highly relevant to plaintiffs' claims that Merck failed to disclose critical safety information about the drug to the medical community.

(Pls.' Mem. at 24.) Thus far, however, there is no reason to believe that Plaintiffs' treating physicians – dentists, oral surgeons, and infectious disease specialists – have "prescribing habits" with respect to Fosamax or any other bisphosphonate. Plaintiffs' insistence that Merck produce

treating physician IMS data thus amounts to yet another demand that Merck expend significant resources searching for records that exist, if at all, only in the rare case.[22] Even if Plaintiffs did not have available to them the readily apparent and more efficient alternative of asking such treating doctors and dentists what they knew about Fosamax (and when) and how that information impacted their prescribing habits, if any, imposing such a burden on Merck simply cannot be worth the scant information such an exercise could be expected to turn up. Yet again, Plaintiffs' argument falls well short of establishing good cause for the discovery sought.

D. Monthly discovery status conferences are unnecessary

In the twenty months since the initial status conference, discovery has proceeded effectively and efficiently, and disputes have reached the point where they required the Court's attention only twice – the instant motion and the cost-sharing dispute resolved last fall. That track record does not justify the additional burden, on the Court or the parties, of the monthly conferences that Plaintiffs propose.

V. CONCLUSION

For all of these reasons, Plaintiffs' Motion to Compel Production of Documents should be denied.

[22] Plaintiffs themselves exclude dentists and oral surgeons from "the types of physicians that prescribed Fosamax . . . ." (*See* Pls.' Mem. at 21.)

DATED: New York, New York
May 12, 2008

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: /s/

Norman C. Kleinberg
Theodore V. H. Mayer
William J. Beausoleil
kleinber@hugheshubbard.com
mayer@hugheshubbard.com
beausole@hugheshubbard.com

Paul F. Strain
M. King Hill, III
David J. Heubeck
Michael B. MacWilliams
VENABLE LLP
Two Hopkins Plaza, Suite 1800
Baltimore, MD 21201
(410) 244-7400
pfstrain@venable.com
mkhill@venable.com
djheubeck@venable.com

Attorneys for Defendant Merck & Co., Inc.